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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,682

Applicant(s)

POND, GARY J.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 11, 16-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 11, 16-18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the biasing member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not provide an antecedent basis for a biasing means, as claimed in claim 23.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2-5, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the limitation "means for receiving the cartridge" in line 7 and again in line 14. It is unclear if Applicant is

Art Unit: 1641

referring to the same means or a second means for receiving the cartridge. (For purposes of examining the claims, Examiner assumes it is the same means, based on Applicant's specification.) Claims 3-5, 7 and 8 are rejected since they are dependent on claim 2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2-5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilmot et al., 6,210,369. Wilmot et al. disclose a syringe (12) for use with a cartridge (14) containing a liquid, the cartridge being closed at one end with a piercable diaphragm (36) and being closed at a second end with a plug (46), the syringe comprising: a syringe body (12), and a means (i.e., interior of 12) for receiving the cartridge; a plunger (22, 118, 138 and 143) within the syringe body; a barrel (24) in the interior of the syringe body, said barrel having an open end (see proximal end of 24), said open end being positioned opposite a protrusion, said protrusion (proximal end of 58) adapted to pierce the diaphragm of the cartridge; and a hollow needle (58) coupled to the open end of the barrel; and wherein said syringe body includes means for receiving the cartridge, said means comprising a longitudinal slot (i.e., interior of 12)

Art Unit: 1641

located on the syringe body between the open proximal end and the oppositely spaced open distal end.

As to claim 3, an o-ring (44) is positioned on the barrel.

As to claim 4, the plunger further comprises a means (143) for providing a breakaway feature intermediate the ends of said plunger.

As to claim 5, the means for providing a breakaway features includes a circumferentially scored groove (143) located intermediate the ends of said plunger.

As to claim 7, a finger rest and handle as claimed is disclosed at (136).

As to claim 8, the plunger further comprises a looped (see distal end of 136) manually operated member.

3. Claims 2, 3, 6, 7, 8 11, 16-17 and 20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu, 5,931,813. Liu discloses a syringe body (21), a plunger (22), a barrel (23), a needle (24), and a means (interior of 21) for receiving a cartridge, said means comprising a longitudinal slot located on the syringe body.

As to claims 3, 11, and 20, an o-ring or sealing means is at (32).

As to claims 6, 11, 16 and 20, a barbed member is at (26), and a gripping feature is at (25).

As to claims 7, 17, 21, a finger rest and handle is at proximal end of (22).

As to claim 23, the biasing member is considered to be(22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8, 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 5,931,813, in view of Janus, 6,068,616. Liu discloses the invention substantially as claimed, see above, except for a looped member. Janus discloses a looped member (8) on the end of a plunger rod for placing a thumb for injection. It would have been obvious to provide a looped member as taught by Janus for thumb placement during injection.

Claims 4, 5, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 5,931,813, in view of Rossi, 5,370,619. Liu discloses the invention substantially as claimed, see above, except for a breakaway feature. Rossi discloses a breakaway feature comprising a circumferentially scored groove (117) to discard the plunger and prevent needle sticks. It would have been obvious to provide a breakaway feature in the Liu device to discard the plunger and prevent needle sticks as taught by Rossi.

Response to Arguments

Applicant's arguments filed March 31, 2003 have been fully considered but they are not persuasive. Applicant argues that Wilmot does not reveal a longitudinal slot or

Art Unit: 1641

opening adapted to receive a single-use drug cartridge and which permits ready access to the interior of the syringe body. In response, Examiner reasserts that interior of (12) constitutes a slot on the syringe body between the open proximal end and the oppositely spaced open distal end.

Applicant's arguments with respect to claims 4 and 5 have been considered but are moot in view of the new ground(s) of rejection, see above.

With respect to the previously indicated allowable subject matter, upon reconsideration, Examiner believes the above rejection is proper. Examiner apologizes for any inconvenience this may have caused. Since Applicant is not positively claiming the cartridge, the prior art only needs to be capable of performing the intended use, i.e., the prior art only needs to be capable of being used with a cartridge as claimed. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-TH 8-6:30.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

June 18, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
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08/R/7